## REMARKS

This Amendment, filed in conjunction with a Request for Continued Examination ("RCE"), responds to the final Office Action mailed 2 November 2007. The filing of this Amendment and RCE is permissible under 37 C.F.R. § 1.114. *See* M.P.E.P. § 706.07(h).

Claims 1, 7, 9, 15, 28, 31, and 47 have been amended and claim 6 has been canceled. Support for these amendments can be found variously throughout the specification; including, for example, page 6, lines 5-6, page 6, line 22 to page 7, line 5, page 9, lines 6-22, FIGS. 1A, 1B, 2A-4A, FIG. 6A, and original claims 6 and 16. No new matter has been added. Accordingly, claims 1-5, 7-33, 37-40, and 42-55 are presently pending in the application, each of which Applicant believes is in condition for allowance. Applicant respectfully requests reexamination and reconsideration in light of the above amendments and the following remarks.

For simplicity and clarity purposes in responding to the Office Action, Applicant's remarks are primarily focused on the rejections applied to the independent claims (*i.e.*, claims 1, 15, 25, 28, 31, 37, 42, 43, 45, 47, and 53) as outlined in the Office Action with the understanding that the dependent claims are patentable for at least the same reasons (and in most cases other reasons) that the independent claims are patentable. Applicant expressly reserves the right to argue the patentability of the dependent claims separately in any future proceedings.

### Allowable Subject Matter

Applicant thanks the Examiner for recognizing claims 3, 6, 7, 9-13, 16-24, 26, 27, 32, 44, and 55 as containing allowable subject matter. With this Amendment, subject matter of claim 6 is incorporated into independent claim 1. Accordingly, withdrawal of the objection to claims 3,

7, and 9-13, which depend from independent claim 1, and allowance of the same are respectfully requested.

Additionally, claims 16-24 depend from independent claim 15, claims 26 and 27 depend from independent claim 25, claim 32 depends from independent claim 31, claim 44 depends from independent claim 43, and claim 55 depends from independent claim 53. As discussed below, each of independent claims 15, 25, 31, 43, and 53 are believed to be in immediate condition for allowance. Accordingly, claims 16-24, 26, 27, 32, 44, and 55 are allowable for at least the reasons set forth below with respect to independent claims 15, 25, 31, 43, and 53. Withdrawal of the objection to these claims and allowance of the same are therefore respectfully requested.

**Claim Rejections – 35 U.S.C. § 112**

In the Action, claim 28 was rejected under 35 U.S.C. § 112, second paragraph, for alleged indefiniteness. Applicant respectfully traverses this rejection. Nonetheless, claim 28 has been amended in a manner obviating the rejection. Withdrawal of this rejection is therefore courteously solicited.

**Claim Rejections – 35 U.S.C. § 102**

In the Action, the Examiner rejected claims 15, 28-30, and 47-52 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 6,425,924 to Rousseau. ("Rousseau"). The Examiner also rejected claims 31 and 33 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,545,178 to Kensey et al.. ("Kensey"). Additionally, the

Examiner rejected claims 53 and 54 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,792,154 to Doan et al.. ("Doan"). Applicant respectfully traverses this rejection.

*Claims 15 and 47-52*

Claim 15 recites, *inter alia*, "an internal component configured to be positioned against an internal wall of a bodily lumen, the internal component comprising a stiff member." Similarly, independent claim 47 recites, *inter alia*, "an anchor configured to be inserted through a tissue puncture, the anchor comprising a stiff member."

In contrast, Rousseau clearly fails to disclose, teach, or suggest each and every element recited in independent claims 15 and 47. For example, at the very least, Rousseau fails to disclose, teach, or suggest an internal component or an anchor comprising "a stiff member." Instead, Rousseau merely discloses a prosthesis that includes flexible, compressible, and expandable mesh cones 14 that may be inserted into a hernia opening in an abdominal wall.

For example, Rousseau clearly states that the "compression of opposing cones 14 causes cones 14 to collapse axially onto themselves, thus causing the diameter of cones 14 to expand radially and pleats 16 to open up or expand into a relatively flattened position." Col. 6, lines 3-9. Rouseau, further states that "the conical mesh is forced into a relatively flat condition. As scar tissue grows into the flattened conical layers, it is compressed further in the axial direction by scar tissue contraction." As Rousseau make clear, mesh cones 14 do not comprise a stiff member, but rather, mesh cones 14 are flexible, compressible, and expandable members.

In fact, Rousseau clearly teaches away from any use of a stiff member. *See, e.g., In re Geisler*, 116 F.3d 1465, 1471, 43 USPQ2d 1362, 1366 (Fed. Cir. 1997). For example, Rousseau states:

> When [the prostheses] is expanded, it relies only on the radial expansion force generated from the compression of the opposing textile cones to enlarge the diameter, as opposed to the use of additional semi-rigid rings or other rigid or semi-rigid members. **Preferably, prostheses of the present invention do not comprise such rigid or semi-rigid devices**. This ensures that the device is fully compliant to the natural anatomical structures.

Col. 6, lines 16-25 (emphasis added). In other words, the prosthesis disclosed in Rousseau explicitly teaches against the use of rigid or even semi-rigid devices in place of, or even in conjunction with, flexible mesh cones 14.

Accordingly, because Rousseau fails to disclose, teach or suggest each and every element of claims 15 and 47, a *prima facie* anticipation rejection has not been established. *See, e.g., Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference"); *see also Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1566 (Fed. Cir. 1989) ("The identical invention must be shown in as complete detail as is contained in the ... claim.") (emphasis added). Applicant therefore respectfully requests withdrawal of this rejection and allowance of the claims.

Moreover, aside from the novel features recited therein, claims 48-52 are also allowable at least by virtue of their dependency upon allowable base claim 47. Applicant respectfully

requests, therefore, that the rejection of claims 48-52 under 35 U.S.C. § 102(b) be withdrawn, and these claims be allowed.

*Claims 28-30*

Claim 28 recites, *inter alia*, that a "filament passes through at least two openings from the first plurality of openings, through the anchor, and back through at least two openings from the second plurality of openings ... wherein the filament weaves between the anchor and the first plurality of openings in a nonlinear pattern."

In contrast, Rousseau fails to disclose, teach, are suggest each an every element recited in independent claim 28. For example, at the very least, Rousseau fails to disclose, teach, or suggest that a "filament weaves between the anchor and the first plurality of openings in a nonlinear pattern." Instead, Rousseau merely discloses a prostheses 10 for closing a hernia opening, the prosthesis including a filament that passes linearly between cones 14 and overlay sheet 26.

For example, Rousseau discusses the path taken by suture 22 between cones 14, stating:

> Suture 22 is passed through the inner diameter of opposing cones 14, passing from the apex of one cone, through the apex of the second. Suture 22 then is looped and returned back through the inner diameter of the prosthesis in the opposite direction.

Col. 5, lines 14-18 (emphasis added); *see also*, FIG. 1. As Rouseau makes clear, suture 22 passes linearly between the apexes of cones 14 in a first direction and then in an opposite direction. Therefore, suture 22 follows a linear pattern between cones 14.

Accordingly, because Rousseau fails to disclose, teach or suggest each and every element of claim 28, a *prima facie* anticipation rejection has not been established. Moreover, aside from the novel features recited therein, claims 29 and 30 are also allowable at least by virtue of their dependency upon allowable base claim 28. Applicant respectfully requests, therefore, that the rejection of claims 28-30 under 35 U.S.C. § 102(b) be withdrawn, and these claims be allowed.

*Claims 31 and 33*

Claim 31 recites, *inter alia*, "an insertion sheath having first and second ends; a carrier tube disposed inside the insertion sheath, the carrier tube having first and second ends; an anchor disposed inside the insertion sheath at the first end thereof, the anchor being disposed outside of the carrier tube at the first end thereof."

Kensey, in contrast, clearly fails to disclose, teach, or suggest each and every element recited in independent claim 31. For example, at the very least, Kensey fails to disclose, teach, or suggest "an anchor disposed inside the insertion sheath at the first end thereof, the anchor being disposed outside of the carrier tube at the first end thereof." Rather, Kensey merely discloses a device in which anchoring member 38 is always outside of sheath 88 when it is outside of deployment instrument 32.

For example, FIGS. 1 and 2 show a device having both anchoring member 38 and deployment instrument 32. In each of FIGS. 1 and 2, deployment instrument 32 protrudes beyond sheath 88 at the distal end, preventing a situation where anchoring member 38 might be located inside sheath 88 and outside of deployment instrument 32. Indeed, Kensey only discloses pushing "the anchoring member 38, to cause the anchoring member to pass out of the

distal end of the instrument and trocar sheath, thereby deploying the anchoring member in the abdominal cavity." Col. 10, line 64 to col. 11, line 4 and FIGS. 1 and 2. After anchoring member 38 passes out of deployment instrument 32 and sheath 88, Kensey teaches that the "deployment instrument and trocar are then withdrawn from the puncture 22." In other words, Kensey clearly teaches that deployment instrument 32 extends beyond sheath 88, and anchoring member 38 is passed out of deployment instrument 32 directly into the abdominal cavity, after which both deployment instrument 32 and sheath 88 are removed from the abdominal cavity, leaving anchoring member 38 in the abdominal cavity.

Accordingly, because Kensey fails to disclose, teach or suggest each and every element of claim 31, a *prima facie* anticipation rejection has not been established. Moreover, aside from the novel features recited therein, claim 33 is also allowable at least by virtue of its dependency upon allowable base claim 31. Applicant respectfully requests, therefore, that the rejection of claims 31 and 33 under 35 U.S.C. § 102(b) be withdrawn, and these claims be allowed.

*Claims 53 and 54*

Independent claim 53 recites, *inter alia*, a "tissue puncture closure device, comprising: an anchor configured to be inserted through a tissue puncture." In contrast, Doan fails to disclose, teach, or even suggest each and every element recited in claim 53.

For instance, Doan fails to disclose, teach, or even suggest either a "tissue puncture closure device" or an "anchor." Instead, Doan merely discloses a vaso-occlusive device 100 that is fully inserted into a vessel to limit the flow of blood in the vessel. Doan additionally teaches that Vaso-occlusive device 100 may have a rounded tip 137.

In the Action, the Examiner argued that Doan shows "a tissue puncture closure device including an anchor (137) configured to be inserted through a tissue puncture." On the contrary, the device disclosed by Doan is not a "tissue puncture closure device," but rather, the device is a "micro-vaso-occlusive device intended generally for occlusion of small arteries located distally in the vasculature." Col. 1, lines 6-8. In other words, rather than being used as a "tissue puncture closure device," the device disclosed by Doan is used to block the passage of blood through targeted blood vessels.

Additionally, Doan fails to disclose, teach, or suggest that "rounded tip 137" is an anchor. Rather, Doan merely states that "[t]ypical use of a coil such as [coil (133)] in which the leading edge of the coil is exposed to the lumen of a blood vessel is the use of a rounded soft tip (135)." Col. 4, lines 47-49 and FIG. 5. From the above Doan appears to suggest that the leading edge of a coil (133) often has a soft tip (135) that may protect the inside of a blood vessel from the leading edge of coil (133). Doan further states that "vaso-occlusive (136) additionally has rounded tip (137) as did the device shown in FIG. 5," indicating that the rounded tip (137) in FIG. 6 is analogous to soft tip (135) shown and described in reference to FIG. 5. Col. 4, lines 60-61. Therefore, as can be seen from the above, Doan fails to even suggest that rounded tip (137) may function as an anchor.

Accordingly, because Doan fails to disclose, teach or suggest each and every element of claim 53, a *prima facie* anticipation rejection has not been established. Moreover, aside from the novel features recited therein, claim 54 is also allowable at least by virtue of its dependency upon allowable base claim 53. Applicant respectfully requests, therefore, that the rejection of claims 53 and 54 under 35 U.S.C. § 102(b) be withdrawn, and these claims be allowed.

**Claim Rejections – 35 U.S.C. § 103**

In the Action, the Examiner rejected claims 1, 2, 4, 5, 8, and 14 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Rousseau in view of U.S. Patent No. 5,116,957 to Eberbach ("Eberbach"). Additionally, the Examiner rejected claims 25 and 43 under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,027,523 to Schmieding ("Schmieding"). The Examiner also rejected claims 31, 37-40, 42, 45, and 46 under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,508,828 to Akerfeldt et al. ("Akerfeldt"). Applicant respectfully traverses this rejection.

*Claims 1, 2, 4, 5, 8, and 14*

As detailed above, independent claim 1 is currently amended to incorporate allowable subject matter of previously presented claim 6. Independent claim 1 is thus allowable for at least for at least the reasons set forth on pages 8-9 of the Office Action.

Moreover, aside from the novel limitations recited therein, dependent claims 2, 4, 5, 8, and 14 are also allowable at least by virtue of their dependency upon allowable base claim 1. Applicant respectfully requests, therefore, that the rejection of claims 1, 2, 4, 5, 8, and 14 under 35 U.S.C. § 103(a) be withdrawn, and these claims be allowed.

*Claims 25 and 43*

Independent claim 25 recites, *inter alia*, "a flexible sealing plug attached to the anchor by the filament." Similarly, independent claim 43 recites, *inter alia*, "a sealing plug that is

compressible; and a filament configured to couple the anchor and the sealing plug together, the sealing plug being configured to compress when a tension force is applied to the filament."

In contrast, Schmieding fails to disclose, teach, or suggest each and every element recited in claims 25 and 43. For example, Schmieding fails to disclose, teach, or even suggest "a flexible sealing plug" or "a sealing plug that is compressible." Instead, Schmieding merely discloses a device use to hold soft tissue to bone.

On page 6 of the Action, the Examiner expressed the opinion that Schmieding discloses "a flexible sealing plug (42) ... where the sealing plug is formed of PLLA, which is an inherently flexible or compressible polymeric material." However, the Examiner has not provided any basis in fact or technical reasoning to reasonably support the conclusion that a PLLA polymer used to form "cross 42," as described in Schmieding, is "an inherently flexible or compressible polymeric material."

According to Federal Circuit precedent, and as emphasized in the MPEP, in order to "establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is **necessarily present** in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999); *accord*. MPEP 2112 (emphasis added). "In relying upon the theory of inherency, the Examiner **must provide a basis in fact and/or technical reasoning** to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of

the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis added).

Schmieding clearly fails to disclose, teach, or suggest that a PLLA polymer used in "cross 42," which is an embodiment of "disk 4," is flexible or compressible. Rather, Schmieding states that "[e]ither or both of disk 4 and suture 6 can be formed of a **biosorbable material**, such as PLLA." Col. 3, lines 24-25. The designation "PLLA" does not specify the physical characteristics and properties of the polymer used to form disk 4, rather, "PLLA" denotes monomer subunits present in the polymer (*i.e.*, Poly-L-Lactide Acid). A significant number of characteristics of the PLLA polymer material mentioned in Schmieding are unknown, each of which might very well be determinative of the PLLA polymer properties. For example, Schmieding does not disclose whether the PLLA is a copolymer containing other monomer units, what the molecular weight of the polymer is, whether the polymer is cross-linked, what the crystallinity of the polymer is, what molding method was used to form the polymer article, what the conditions used to process the polymer were, etc. Additionally, Schmieding does not disclose the dimensions or size of cross 42, which would likely affect its relative rigidity or compressibility of cross. For example, a thin suture 6 formed of one PLLA polymer might be flexible because of its thin dimensions and particular set of polymer characteristics, while a cross 42 formed of a separate PLLA polymer might be rigid because of its larger dimensions and differing set of polymer characteristics. Essentially, the designation "PLLA" does not support a conclusion that cross 42 is inherently flexible or compressible.

In addition, not only has the Examiner failed to establish that cross 42 is inherently flexible or compressible, Schmieding clearly teaches against forming cross 42 from a flexible or

compressible material. Schmieding states that "[d]isk 4 alternatively can be made of a plastic material such as Delrin." Col. 3, lines 27-28. Delrin® is an acetal resin manufactured by DuPont. DuPont states on their website (http://plastics.dupont.com/myplastics/Mediator?id=30) that "Delrin® bridges the gap between metals and ordinary plastics with a unique combination of strength, **stiffness, hardness, dimensional stability, toughness**, fatigue resistance, solvent and fuel resistance, abrasion resistance, low wear and low friction." *See* Appendix (emphasis added). Delrin is clearly not a flexible or compressible material, but rather, is a stiff, hard, and tough material.

Schmieding further indicates that cross 42, which is an embodiment of disk 4, is not a flexible or compressible article. For example, FIG. 1 shows disk 4 being used to "approximate soft tissue to bone." Col. 3, lines 6-10. As can easily be seen in FIG. 1, disk 4 compresses the "soft tissue," while disk 4 itself is neither bent nor compressed.

Moreover, cross 42, as disclosed in Schmieding, does not even function as a "sealing plug," but rather, is merely used as a "tissue-fixation disk." Col. 1, lines 13-16. In fact, Schmieding clearly teaches away from the use of cross 42 as a sealing plug. As mentioned above, disk 42 is an embodiment of disk 4, which has a "drive socket 14" that is a hole right in the middle of disk 4. Col. 54-55 and FIG. 4. Likewise, other embodiments of disk 4 have large open holes or spaces, including "ring 40" and "bended bar 46." Col. 4, lines 60-61 and FIGS. 10 and 13. As is clear from the foregoing, disk 4, and likewise cross 42, does not function as a "sealing plug." Instead, disk 4, and likewise cross 42, merely functions to secure "soft tissue to bone." Col. 1, lines 13-16 and FIG. 1.

Accordingly, because Doan fails to disclose, teach or suggest each and every element of claims 25 and 43, a *prima facie* case of obviousness has not been established. *See, e.g., In re Royka*, 490 F.2d 981, 985 (CCPA 1974) (holding that to establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art); *accord.* MPEP § 2143.03 ("To establish a *prima facie* case of obviousness ... the prior art reference (or references when combined) must teach or suggest all the claim limitations.") (emphasis added). Applicant respectfully requests, therefore, that the rejection of claims 25 and 43 under 35 U.S.C. § 103 be withdrawn, and these claims be allowed.

*Claim 31*

Independent claim 31 recites, *inter alia*, "an insertion sheath having first and second ends; a carrier tube disposed inside the insertion sheath, the carrier tube having first and second ends; an anchor disposed inside the insertion sheath at the first end thereof, the anchor being disposed outside of the carrier tube at the first end thereof" and "a sealing plug disposed inside the carrier tube at the first end thereof, wherein the sealing plug is folded at least once."

Akerfeldt, in contrast, clearly fails to disclose, teach, or suggest each and every element recited in independent claim 31. For example, at the very least, Akerfeldt fails to disclose, teach, or suggest "a carrier tube disposed inside the insertion sheath." Rather, Akerfeldt merely discloses a wound closure device comprising an introducer 24, with no "carrier tube disposed inside" the introducer 24.

For example, FIG. 8 "shows a wound closure device, which comprises ... a pusher 22 adapted for pushing the first sealing member 2, the elongated member 4 and the second sealing

member 6 through an introducer 24." Col. 6, lines 9-13. In other words, Akerfeldt merely discloses a wound closure device comprising an introducer 24 but no "carrier tube." Additionally, since Akerfeldt fails to disclose, teach, or suggest a "carrier tube," Akerfeldt also clearly fails to disclose, teach, or suggest "a sealing plug disposed inside the carrier tube at the first end thereof; wherein the sealing plug is folded at least once."

Additionally, Akerfeldt clearly fails to disclose, teach, or suggest "a sealing plug" that "is folded at least once." On page 7 of the Action, the Examiner expressed the opinion that Akerfeldt teaches "a sealing plug (18) that is folded at least once." However, the Examiner misconstrued "elongated core 18" in Akerfeldt as being a sealing plug. Akerfeldt makes clear that elongated core 18 is not a sealing plug, but rather, elongated core 18 is thickened portion of suture wire 12 that "gives the suture wire 12 a thickening in the distal lock portion 16." Col. 5, lines 4-7. Akerfeldt explains the purpose for the thickening in the distal lock portion 16, stating:

> The most distal portion of the elongate member 4 has a constant thickness that is slightly greater than the opening 14 of the second sealing member 6 and constitutes the distal lock portion 16.
>
> This will allow for **frictional engagement** between inside of the opening 14 of the second sealing member 6 and the distal lock portion 16 of the elongate member 4 ...

Col. 4, lines 21-28 (emphasis added). In other words, as Akerfeldt makes clear, elongated core 18 is not sealing plug, but rather, is merely a component used to thicken distal lock portion 16, enabling distal lock portion 16 to frictionally engage and secure sealing member 6. As further evidenced in FIGS. 1, 2, 6, 7, and 12-17 of Akerfeldt, elongated core 18 merely occupies a small portion of a wound in a vessel wall, and accordingly, elongated core 18 cannot function as a

sealing plug. Therefore, in light of the fact that elongated core 18 is not a "sealing plug," Akerfeldt fails to otherwise disclose a "sealing plug" that "is folded at least once."

Accordingly, because Akerfeldt fails to disclose, teach or suggest each and every element of claim 31, a *prima facie* case of obviousness has not been established. Applicant respectfully requests, therefore, that the rejection of claim 31 under 35 U.S.C. § 103 be withdrawn, and this claim be allowed.

*Claims 37-40*

Independent claim 37 recites, *inter alia*, a "method of sealing an internal tissue puncture," that uses "a sealing plug" that "is folded so that one portion of the sealing plug is in contact with another portion of the sealing plug." Claim 37 further recites "filling the internal tissue puncture with the sealing plug."

Akerfeldt, in contrast, clearly fails to disclose, teach, or suggest each and every element recited in independent claim 37. For example, at the very least, Akerfeldt fails to disclose, teach, or suggest "a sealing plug" that "is folded so that one portion of the sealing plug is in contact with another portion of the sealing plug." As discussed in detail above in reference to independent claim 31, elongated core 18 is not a "sealing plug," but is merely a component used to thicken distal lock portion 16, enabling distal lock portion 16 to frictionally engage and secure sealing member 6. It follows, therefore, that Akerfeldt also fails to disclose, teach, or even suggest a "sealing plug" that "is folded so that one portion of the sealing plug is in contact with another portion of the sealing plug."

Additionally, as evidenced in FIGS. 1, 2, 6, 7, and 12-17 of Akerfeldt, elongated core 18 merely occupies a small portion of a wound in a vessel wall. Therefore, Akerfeldt fails to disclose, teach, or even suggest "filling the internal tissue puncture with the sealing plug."

Accordingly, because Akerfeldt fails to disclose, teach or suggest each and every element of claim 37, a *prima facie* case of obviousness has not been established. Moreover, aside from the novel limitations recited therein, dependent claims 38-40 are also allowable at least by virtue of their dependency upon allowable base claim 37. Applicant respectfully requests, therefore, that the rejection of claims 37-40 under 35 U.S.C. § 103(a) be withdrawn, and these claims be allowed.

*Claim 42*

Independent claim 42 recites, *inter alia*, "a sealing plug" that "is folded at least once so that one portion of the sealing plug is in contact with another portion of the sealing plug."

Akerfeldt, in contrast, clearly fails to disclose, teach, or suggest each and every element recited in independent claim 42. For example, at the very least, Akerfeldt fails to disclose, teach, or suggest "a sealing plug" that "is folded at least once so that one portion of the sealing plug is in contact with another portion of the sealing plug." As discussed in detail above in reference to independent claim 31, elongated core 18 is not a "sealing plug," but is merely a component used to thicken distal lock portion 16, enabling distal lock portion 16 to frictionally engage and secure sealing member 6.

It also follows, based at least on the fact that elongated core 18 is not a "sealing plug," that Akerfeldt also fails to disclose, teach, or even suggest a "sealing plug" that "is folded so that one portion of the sealing plug is in contact with another portion of the sealing plug."

Accordingly, because Akerfeldt fails to disclose, teach or suggest each and every element of claim 42, a *prima facie* case of obviousness has not been established. Applicant respectfully requests, therefore, that the rejection of claim 42 under 35 U.S.C. § 103(a) be withdrawn, and this claim be allowed.

*Claims 45 and 46*

Independent claim 45 recites, *inter alia*, "a sealing plug that is generally V-shaped when the sealing plug is open and laid out flat" and "wherein the tissue puncture closure device is configured so that applying a tension force to the filament compresses and holds the sealing plug and the anchor together."

Akerfeldt, in contrast, clearly fails to disclose, teach, or suggest each and every element recited in independent claim 45. For example, at the very least, Akerfeldt fails to disclose, teach, or suggest "a sealing plug that is generally V-shaped when the sealing plug is open and laid out flat." As discussed in detail above in reference to independent claim 31, elongated core 18 is not a "sealing plug," but is merely a component used to thicken distal lock portion 16, enabling distal lock portion 16 to frictionally engage and secure sealing member 6. It follows, therefore, that Akerfeldt fails to disclose, teach, or even suggest a "sealing plug that is generally V-shaped."

It also follows, based at least on the fact that elongated core 18 is not a "sealing plug," that Akerfeldt also fails to disclose, teach, or even suggest a "tissue puncture closure device" that

is "configured so that applying a tension force to the filament compresses and holds the sealing plug and the anchor together."

Accordingly, because Akerfeldt fails to disclose, teach or suggest each and every element of claim 45, a *prima facie* case of obviousness has not been established. Moreover, aside from the novel limitations recited therein, dependent claim 46 is also allowable at least by virtue of its dependency upon allowable base claim 45. Applicant respectfully requests, therefore, that the rejection of claims 45 and 46 under 35 U.S.C. § 103(a) be withdrawn, and these claims be allowed.

**Conclusion**

For at least the foregoing reasons, Applicants believe that each of the presently pending claims in this application is in immediate condition for allowance. Accordingly, Applicants respectfully request a favorable action on the merits. If the Examiner has any further comments or suggestions, Applicants invite the Examiner to telephone the undersigned attorney to expedite the handling of this matter.

Respectfully submitted,

Dated: 2/4/2008

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